An air assistance apparatus for computing the airflow provided by only means of pressure sensors

Technical field

This invention concerns the field of apparatus to assist a patient respiration and more specifically an apparatus able to calibrate the tubes connected to the patient's mask and to the blower and to determine the airflow of the patient's from pressure measurement and from the tube calibration.

Background art

In many treatments apparatus are used to provide patients with air. More frequently it is used for patients with a breathing deficiency caused for example by the weakness of the breathing system or by obstructive apneas during the sleep. In those cases it is important to control the pressure of the air delivered to the patient. With respiratory insufficient patients, apparatus providing air at a higher pressure help to compensate the weakness of the patients lungs. In the case of patients suffering of sleep apneas, providing the air at a higher pressure removes the obstruction of the upper airways.

In order to provide a correct treatment, it is required to accurately know the value of airflow the patient is provided with. Usually the apparatus determine the airflow by measuring airflow in the patient circuit (between the blower and the mask) using an airflow sensor. Airflow sensors can be based on high sensitivity differential pressure sensors measuring the pressure drop across a low resistance or using pitot tubes, or hot wire airflow sensors. Another commonly used mean to evaluate the airflow is by measuring the blower parameters such as speed, current consumption and power.

Summary of the invention

The first object of the invention is to determine the airflow at the patient's mask, without using sensors like airflow sensors that are expensive or motor consumption or rotation sensors that are not accurate especially at low flows.

The invention thus concerns to assist a patient respiration by delivering air to a patient trough a mask, said mask being designed to be connected on one first extremity of a tube, said apparatus comprising :

- a control unit to adjust the pressure delivered by the blower of said apparatus,
- a first pressure sensor for sensing the pressure PM at the first tube extremity and being connected to the control unit, and
- a second pressure sensor for sensing the pressure PB at the air output of said blower and being connected to said control unit.

These elements are comprised in the apparatus in order that, when a tube is connected to the mask and connected to said apparatus on its second extremity, the air flowing from the apparatus to the mask, said control unit is able to calculate the airflow at said second extremity of the tube from the pressures PM and PB and from the airflow resistance coefficient K_T of the tube

An other implementation of the apparatus according to the invention is to provide an apparatus being able to calculate the coefficient K_T by using a shell with a traversing hole having a known airflow resistance coefficient K_s. This enables to use tubes of different sizes, and even tubes with different standards of airflow resistance coefficients.

A further implementation of the apparatus according to the invention is that the pressure control unit comprises an estimation module connected to the means for detecting the patient's breathing parameters, in order that the estimation module is able to determine when the patient is inspiring or

expiring and in response the pressure to apply to the patient's mask, so that the control unit adjust the pressure delivered by the blower.

Further implementations enable to modulate the pressure of the provided air in response to the patient's breathing parameters and events which occur in the patient's breathing.

Brief description of figures

The purposes, objects and characteristics of the invention will become more apparent from the following description when taken in conjunction with the accompanying drawings in which:

Figure 1 represents the apparatus according to the present invention when used according to a preferential implementation,

Figures 2 represents the flowchart of the calibration of a tube by the apparatus,

Figure 3 represents a device of the apparatus according to present invention,

Figure 4 represents the electric schema of the device represented in figure 3,

Figure 5 represents an implementation of the apparatus,

Figure 6 represents the way the apparatus reacts to events occurring in patient's breathing, and

Figure 7 represents how the apparatus operates to detect the presence of a patient at the mask.

Detailed description of the invention

Ordinary tubes used in air assisting apparatus usually comprise a pressure sensing tube to measure the pressure at the end of the tube. The apparatus according to the present invention is based on this characteristic. As represented on figure 1, the apparatus 1 is connected to the tube 20 by the air inlet and connected to the pressure sensing tube of the tube. The pressure sensing tube is connected to a first pressure sensor 6 comprised in the apparatus. If no sensing

tube is comprised, a mean will be connected at a first pressure sensor of the apparatus. Because the tube 20 diameter value is much smaller than the tube 20 length value, the pressure drop in the tube is defined by the following equation:

$$\Delta p = K_T \bullet airflow^2$$

wherein :

K_T represents a constant coefficient characteristic of the tube,

Δp represents the difference of pressure between the two tube extremities, and

airflow is the volume of air per time crossing the tube.

The apparatus has sensors that measure the pressure PB at the apparatus air outlet. As the apparatus is sensing pressure on both sides of the tube, knowing the tube coefficient k is allowing the system to compute the airflow by measuring the pressure drop. The present implementation consists in operating in a mode where precise airflow is required. A shell 10 which is a cap which comprises a small hole 12 at his top is placed to close one extremity of the tube, the other extremity of the tube being connected to the air outlet of the blower 4 of the apparatus 1. This calibration shell 10 has an airflow resistance coefficient K_S which is a characteristic of it.

Considering that PB being the pressure sensed at the output of the apparatus and PM being the pressure sensed at the calibrated termination, S0 being known, we have :

$$Airflow = K_S \bullet \sqrt{PM}$$

as $\Delta p = K_T \bullet airflow^2$ then $K_T = \dfrac{(PB - PM)}{(K_S{}^2 \bullet PM)}$

The apparatus is thus able to determinate the tube coefficient K_T.

The calibration process takes advantages of having a number of measurements made at different pressures levels and by averaging them can get a more accurate K_T value.

Example of a 1.8m tubing Ø15mm:

The calibration termination has a ***S0*** coefficient of **18** (airflow units are in LPM)

PB is measured at **9.90** hPa

PM is measured at **7.72** hPa

This is giving k=**0.000871**

Meaning then that the airflow is : **50.02** LPM

When using a new tube, the calibration process is entered, notably at the request of a clinician or a qualified user. The apparatus is expecting the calibration shell to be hooked as described in figure 1. The flowchart represented in figure 2 is showing an example of a series of measurements resulting on the K_T coefficient calculation, then the tube coefficient K_T is recorded and all the upcoming sessions will be based on this new tube coefficient. When the tube 20 and the shell 10 are installed, the value J corresponding to the number of one measure is set equal to 1 and associated to a number I corresponding to the value of the pressure provided by the blower 4, this I number being for example equal to 4 hPa when the calibration starts. Then the Pulse Width Modulation voltage is applied in order to deliver the pressure PM sensed at the calibrated termination which is the shell 10. The pressure PM and the pressure PB are measured and associated to the J number corresponding to the measure. If J does not equals the number of measures N required to calculate the K_T average, the next measure is taken which means that J is incremented of 1. The next measure is preferentially made for a pressure incremented of 2 hPa, which means that I is incremented of two. When the number of measures required N is reached, the data associated to each measure are computed and enable to associate a tube coefficient K_T value to each corresponding measure J. This enables to calculate an average of the K_T value. For example if eight measures are required, J and I will be incremented 7 times before calculating the tube coefficient k value. This also enables to reject the tube if

its standard does not correspond to the kind of tube which can be used with the apparatus 1. The K_T value will then be used for the airflow computation.

The apparatus according to any of the previous claims, wherein the control unit comprises offset compensation means for compensating the possible difference of gauging between the two pressure

Another embodiment of the present invention is improving the sensitivity of the airflow measurement at low values, by gauging the pressure sensors.

Low flows accuracy is important in air delivery apparatus specially when triggering between inspiration and expiration where sensitivities as low as 5 l/mn are required.

A classical 22mm diameter breathing tube will present a pressure drop (PB-PM) of 0.01 hPa with an airflow of 5 l/mn, so it is mandatory to consider a signal amplification after the subtraction.

But this amplification cannot be done without a prior offset compensation. The apparatus according to the preferential implementation enables to correct this difference of gauging.

As previously described, using two pressure sensors at both ends of a breathing circuit tube, can give an accurate value of airflow., but due to physical constraints, for low flows accuracy, there is a need for amplification.

Due to the manufacturing process of airflow sensors, most of them are presenting a Voltage vs. Pressure relationship like:

$$Vout = Voffset + Kps \bullet \mathrm{Pr}$$

With

Vout being the output voltage

Voffset being the constant that can change drastically from one sensor to another within the same lot and that drifts slowly due to aging

Kps : the gain in volts/hPa of the pressure sensor that is usually stable.

Pr : the difference between pressure sensors 6 and 8

Given the previous equation, subtracting the two voltages of the two pressure sensors will then give:

$$VPbPm = VoffPm - VoffPb + Kps * (Pb - Pm)$$

With

VPbPm is the Voltage result of the subtraction

VoffPm is the offset of the Pm pressure sensor

VoffPb is the offset of the PB pressure sensor

Kps is the gain in volts/hPa of the pressure sensors

By offset it is mean the constant which corresponds to the difference between the pressure measured by one sensor and the absolute value of pressure.

The invention takes advantages of a well know state of the apparatus when no patient is connected to the apparatus, and no pressure is generated by the blower. During this state The PM and PB values have the same value than the ambient pressure. The control unit 2 comprises offset compensation means for compensating the possible difference of gauging between the two pressure sensors 6 and 8.

Preferentially the offset compensation means comprise :

- a digital to analog converter 32 connected to a microprocessor 30 in order to convert microprocessor's digital data in analog data,
- an analog substractor 34 having inputs connected to the second pressure sensor, to the first pressure sensor, and to said digital to analog converter;

said microprocessor calculating, when the blower is not functioning, the difference between the two pressures measured by said first and second pressure sensors and then sending the value C of this difference to said digital to analog converter, which converts said value C in analog data and drive it to said analog subtractor, which subtract the

pressure P_B measured by said second pressure sensor and said value C to the pressure P_M measured by said second pressure sensor and send the corresponding result D to the microprocessor, which will modify the C value until said D result equals zero, said microprocessor capturing the C value when said D result equals zero, enabling the microprocessor which uses the pressure sensors to control the apparatus to correct the difference of offsets between the pressure sensors.

Preferentially the apparatus comprises an analog amplifier 36 connected said analog subtractor 34 in order to amplify the signal corresponding to said D result and to send it to the microprocessor 30, thus enabling the microprocessor to have an accurate adjustment of said value C until the result D reaches the value zero.

The apparatus can also comprise analog to digital converters 42, 44 and 40 connected between the microprocessor 3) and the said first pressure sensor, between the microprocessor and the said second pressure sensor, and between the microprocessor and the said analog amplifier, so that the microprocessor is provided with only digital data.

With a non standard calibration tube, the process for calibrating a tube used in apparatus to assist patient's respiration, comprising :

- connecting a first tube's 20 extremity to the blower of an apparatus according to any of claim 1 to 5,
- if the tube is not provided with a pressure sensor at its second extremity, placing said second pressure sensor at said second extremity,
- connecting said second extremity to a shell 10 with a traversing hole 12 having a known airflow resistance coefficient K_s,
- switching the blower on, and instructing said control unit 2 to measured the pressures on both said first and second pressure sensors,

- calculating the value of the tube airflow resistance coefficient K_t from these measured pressures and from the said coefficient K_s.

The apparatus can also comprise a Frequency Shift Keying (FSK) modulator which transforms the binary data send by the apparatus sensors or elements in a modulation of the frequency of the tension applied on a voltage controlled current source, connected to the external power supply, so that the voltage controlled current source transmit the modulation corresponding to the data, a FSK demodulator converting the voltage frequency modulation into binary data and transmit to the elements, so that each sensor or module connected to the power source is able to receive or transmit information.

The apparatus can also be used in a set for calibrating a tube used in apparatus to assist patient's respiration comprising the apparatus according to present invention and a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_s.

The apparatus enables to modulate the pressure to the patient in respect to the illness to treat. Due to the airflow computation, the apparatus has the capacity to differentiate the two basic states of the respiration: inspiration and expiration. The sensors provided in the apparatus enables the pressure control unit to control the pressure of the air delivered. The outputs of the E Estimator are the value of the inspiration pressure PI which is the pressure maintained at the patient's mask during the inspiration, and the value of the expiration pressure PE which is the pressure maintained at the patient's mask during the expiration. The data of the pressures PM and PB which are sensed at the extremities of the tube and the data of the tube coefficient K_T enable the airflow computation. This computation enables the

computation of the inspiration and expiration, this latest computation enables the estimation module 100 to determinate, which step of the patient's breathing is occurring. A breath estimation step is qualifying a breath in shape, energy (volume) and frequency. The clinician or a qualified user enters parameters of the delivered pressures for the expiration phase and the inspiration phase. The clinician enters also parameters defining how the estimation module 100 is going to react following events detected in the breath estimator. It is well known that a feedback of the patient with his treatment is helping compliance, thus the patient can have an access to a parameter ranging from min to max that is qualified to be "comfort vs. efficiency". This patient setting is having the weight that the clinician is giving to it, from pure placebo effect to some level of effects. Basically the patient settings are applied in the normal breath situation or/and have a limited action on the pressure regulation. It is also possible that the airflow is an input to the estimation module 100. Thus, with the data inputs concerning the breath estimation (and clinical symptoms or event associated with), the inspiration/expiration computation and the clinical settings, and possibly the airflow computation and patient settings, the control unit 2 by the estimation module 100 is able to determinate the pressures required PI and PE. Those two values can be addressed to two different outputs where a switch is able, relative to the inspiration/expiration computation, to connect to the required output regarding if the patient is breathing in or out. The control unit 2 comprises a pressure control loop which, by comparing the pressure measured in the mask and the value of pressure required PI or PE, is able to adjust the tension PWM in order to obtain the correct pressure in the mask. The figure 6 represents one pattern of the pressure of treatment provided according to the airflow due to the patient breathing. In this

example, the clinical technician has set a special modulation of pressures Pi and Pe during respectively the inspiration and the expiration; after a while as no special event occurs the values of the two pressures are changed.

The apparatus has a two steps strong recognition process in order to prevent false start of the apparatus when the mask is not on the patient's face and to prevent starting a new treatment session. When the apparatus is started by the patient by using the keyboard, for example and as represented in figure 7 by using the start key, the blower 33 is kept turning at a very low speed, waiting for some activity on the mask pressure sensors 6. When an activity is detected, the apparatus is instantaneously trying to bring the pressure at the apparatus outlet at a minimum starting pressure SP of 4 hPa. When this pressure is reached the apparatus tries to identify at least one breath to start the process according to the settings. When the mask is not applied against something, like a hand or the patient's face, no activity is detected. Then if a maximum time since the apparatus start has been spend (the timeout is reached) then the blower is stopped. On the contrary, the apparatus keeps on waiting for an activity on the pressure sensors. When the mask is not applied correctly the pressure can not reach 4 hPa. Then if the timeout is reached the blower is stopped, on the contrary the apparatus waits to detect some activity on the pressure sensors. When the mask is not applied on the patient's face no breath pattern is recognized. Then the blower is stopped if the timeout is reached. On the contrary the apparatus waits to detect some activity on the pressure sensors. The timeout checking prevents the blower keeping turning on if the patients does not start the treatment and forget to start the blower. A further advantage of this implementation is that if a patient is connected, bringing the pressure instantaneously to 4 hPa will prevent CO_2 rebreathing.

The following examples demonstrates the way the estimation module 100 modulates the pressure value P_M to apply to the patient's mask.

Example 1 : Variations of the pressure of the average pressure of treatment as a function time according to detected events

In a preferential embodiment the average pressure of treatment on one breathing step is not constant in time and will be modulate by the estimation module 100 according to the events occurring, such as snoring or apneas.

The apparatus will try to reduce the average pressure of treatment value, thus enhancing the patient comfort while breathing against the apparatus. The clinician set a minimum average pressure of treatment Ptmin and a coefficient N_{OEK} expressed in hPa/s.

As represented on figure 6 , when no events are detected the average pressure of treatment value will follow the equation:

$$PT(t) = MAX(PT(t-\varepsilon) - (NOEK \times \varepsilon), PT\min)$$

ε being the sampling time, the MAX function is returning the greatest value of its two members.

The average pressure value PM, corresponding to the pressure of treatment PT on one breath thus decrease linearly until it reaches the minimum set by the clinician and stays constant until an event occurs. The average pressure is change each sampling time which correspond to one single breath (one inspiration and one consecutive expiration).

If an event is detected, a 3 steps process is initiated:

- Step 1: the estimation module, looking in the clinical settings is defining if the event has to affect the average value of pressure PT.

- Step 2 : If so the estimation module looking in clinical settings, will define a persistence delay D_P.

In the example of figure 6 a snore is detected, the persistence delay could be set to 2 minutes.

- Step 3 : A **Ek** parameter in hPa/s is extracted from clinical settings and balanced with an eventual ongoing event. The estimation module will determine the Ek corresponding to the event which occurs or has occurred and linearly increase the average pressure of treatment with Ek as slope coefficient. AVP will then follow the equation:

$$PT(t) = MIN(PT(t-\varepsilon) + (EK \times \varepsilon), AVP\max)$$

ε being the sampling time, the MIN function is returning the smallest value of its two members.

During the persistence delay even if no event occurs the estimation module will keep on increasing the average pressure of treatment PT.

Example 2 : d1, d2 auto adjustment

On the figures 6 d1 and d2 have two different behaviors, according to t2 and t4 definitions. **t2** is defined when the absolute value of airflow starts to decrease within the inspiration phase or shows a fixed delay after t1. **t4** is defined when the absolute value of airflow starts to decrease within the expiration phase or shows a fixed delay after t3.

If t2 and t4 are defined according to the airflow waveform then no auto-adjustment is occurring. If not, following the same rules than AVP, the d1 and d2 can also be affected by the events. In the case when d1 & d2 are not locked by the breath waveform following the same process, d1 & d2 can also be adjusted according to events in the case.